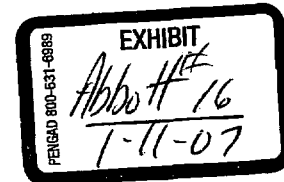
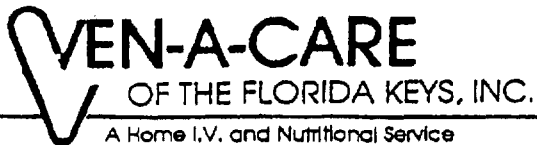


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FAX TRANSMITTAL SHEET

"PERSONAL AND CONFIDENTIAL"

TO: Mr Keith Lynn

AT: Senate Finance Committee

FAX NO: 202-228-3904

FROM: Zach Bentley

FAX NO: 305-292-1739

DATE: 6/25/96 TIME: _____

RE: Billion dollars + ANNUAL loss to the Medicare
& Medicaid programs thru Fraud & Abuse while the
DOS & HHS stand by & watch the thieves "Rob
The Bank"

PAGES TO FOLLOW INCLUDING COVER SHEET: 7

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Hooked on Drugs

Why do insurers pay such outrageous prices for pharmaceuticals?

HIGHLY CONFIDENTIAL

R2-038153

BY BILL ALPERT • Jim Fanning saw the plaque in a doctor's splendid home: "This is the house that leucovorin built." Leucovorin is one of the cancer drugs that typifies a basic drug-industry pricing convention that, in Fanning's view, is a multibillion-dollar fraud. Fanning, the pharmacy director of Fort Worth-based ChemoLab, isn't alone in criticizing the published

wholesale prices that most insurers, public and private, use in determining how much to pay for pharmaceuticals. For many drugs, especially the growing number coming off patent and going generic, the drug providers actually pay wholesale prices that are 60%-90% below the so-called average wholesale price, or AWP, used in reimbursement claims.

But Medicare, one of the largest insurers that still reimburses at AWP, is about to demand a change. The huge federal health-insurance program, trying to forestall insolvency, soon will propose regulations aimed at cutting the amount it lays out for the nearly \$2 billion in annual drug claims it covers outside of hospitals. The move — especially if it is followed by others now paying near AWP for drugs — will attack from a new direction the pricing practices of a drug industry already beset by antitrust suits from retail drugstores. It also could upset a large segment of the health-care industry, which has thrived on the huge spread between the published wholesale prices used in insurance claims and the far lower wholesale prices actually paid.

That segment includes oncology practices, respiratory therapy firms and home-infusion companies. It also includes the drug makers themselves, whose allegedly inflated price lists and the opportunity for profiteering that they afford to middlemen, gain them market share and encourage overuse of their products. Among the publicly traded companies that could be affected: Apria Healthcare Group, Lincare Holdings, RoTech Medical, OmniCare, Abbott Laboratories and Baxter International.

Most people don't even know that Medicare pays for pharmaceuticals and related products, but through piecemeal congressional authorizations, the program now covers certain drugs for emphysema, cancer, kidney dialysis and organ transplantation, often requiring injection. While still barely 1% of its nearly \$184 billion in 1996 spending, Medicare's outpatient drug bill (not including co-payments) was \$1.8 billion last year, double 1992's level.

Under its current regulations, Medicare provides reimbursement for those drugs at the lesser of either its estimate of what the drugs cost the doctors or the Average Wholesale Price.

But Medicare's attempts to survey

doctors for their costs have been stymied by federal paperwork rules, so it reimburses at the AWP.

Like most drug buyers focused on average wholesale price, Medicare looks to compendia such as the *Red Book*, put out monthly by Medical Economics, of Montvale, N.J., or the rival *Blue Book* published by First DataBank, a Hearst subsidiary in San Bruno, Calif. Only after Medicare's drug bill started to rocket did policy makers at the Department of Health and Human Services start closely scrutinizing their AWP payments.

They've asked the department's inspector general's office to examine how Medicare suppliers' true acquisition costs square with the program's reimbursement levels.

Claims for nebulizer drugs, which are in the inhalants used by many asthma and emphysema sufferers, were the first studied by the auditors. From under \$80 million in 1992, Medicare's annual bill for inhalation drugs grew to \$250 million last year, most of it for a

steroid called albuterol sulfate.

In a report released Thursday, the inspector general's office stated that the medical-equipment firms that Medicare reimburses at an average wholesale price-derived 40-43 cents per milliliter actually paid less than half that, on average: just 19 cents. These companies include Apria, LinCare and RoTech.

The report asserted that Medicare could have saved about \$94 million if its reimbursements had been based on actual wholesale prices over the 14 months covered by the study.

Another report by the inspector general produced a similar finding for feeding-tube liquids, like the market-leading Ensure products of Abbott Labs. These, the IG found, cost nursing homes 42% less than the price that Medicare bases its reimbursements on. Such products cost Medicare and its beneficiaries several hundred million dollars a year.

The inspector general currently is looking at prices for big-ticket drugs and intravenous liquids, too. *Barron's*

AWP: AIN'T WHAT'S PAID

► A sample of drugs whose published Average Wholesale Price is wildly above the wholesale price available to almost any buyer. Some of these AWP's actually have risen, while real wholesale prices have plummeted. Publishers say drug makers dictate AWP's.

Drug	Use	Maker	'95 AWP	Wholesale Price	% Under AWP
Doxorubicin HCL powder, 10 mg injectable	Chemotherapy	Adria Labs*	\$46.00	\$13.00	72%
Etoposide 100 mg in 5 ml for injection	Chemotherapy	Gensia	141.97	34.00	76
Gentamicin Sulfate, 100 mg in 10 ml injection	Antibiotic	Abbott	6.18	1.26	80
Intravenous Immune Globulin, 10 mg	Chemotherapy	Baxter	640.71	266.00	58
Leucovorin Calcium, 350 mg injection	Chemotherapy	Immunex	137.94	22.50	84
Methotrexate 250 mg injection	Chemotherapy	Chiron	26.88	6.40	76
Vancomycin HCL 5 gm in 100 ml injection	Antibiotic	Abbott	135.99	36.00	74
Vincristine Sulfate 1 mg injection	Chemotherapy	Eli Lilly	34.62	6.72	81
8.5% Amino Acid sol., 1000 ml for parenteral nutr.	TPN	Abbott	152.65	10.81	93
50% Dextrose Sol., 500 ml in glass	Intravenous Sol	Baxter	27.03	2.56	91
Lactated Ringer's Injection, 500 ml	Intravenous Sol	Baxter	11.16	1.61	86
Normasol 500 ml	Intravenous Sol	Abbott	16.86	2.04	88
Potassium Phosphate, 15 ml vial	Intravenous Sol	Abbott	5.55	0.48	91

* Unit of Pharmacia-Upjohn

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Sources: 1995 Red Book, Florida Infusion, UltraCare

has done the same, in an examination of the top 20 Medicare drugs (which account for about 75% of the program's drug spending), as well as for various intravenous solutions. Our study shows that for many drugs coming off-patent, the average wholesale prices in no way represents the true wholesale price.

For about 300 dose forms of the drugs, *Barron's* got the AWP's from the *Red Book* and the *Blue Book*. Then, we collected current quotes or price lists from several leading wholesalers specializing in selling to doctors, home health firms, nursing homes and hospitals.

These wholesalers included: The Oncology Therapeutics Network, a South San Francisco-based joint venture of Bristol-Myers Squibb and Axion; Florida Infusion Services of Palm Harbor, Fla.; National Specialty Services, of Nashville; and UltraCare, of Overland Park, Kan. Prices also came in from the Boulder, Colo., hospital buying group Vista Purchasing Partners.

This sampling showed that for single-source drugs still enjoying patent protection, such as Bristol-Myers Squibb's Taxol or Platinol, true wholesale prices are generally 10%-20% below published AWP's.

But for generic drugs, nearly every manufacturer's price was 60%-85% below the published average wholesale price. Some of the generics account for significant spending by Medicare, claiming half of the top 20 slots. Two of them, albuterol and leukovorin, are in the No. 2 and No. 5 slots, respectively.

The pricing unreality is even worse for intravenous nutritionals and solutions, a category dominated by Abbott Laboratories and Baxter International. Catalog wholesale prices for these items are, on average, 80%-93% below those companies' AWP's.

The prices from the different wholesalers were closely bunched. "There are really no special deals out there," contends Fanning, who buys plenty of drugs at wholesale himself.

If most health-care providers can get these prices, is it any wonder an industry wag says that AWP really means "Ain't What's Paid"?

The high prices on generic drugs have led investigators to seek the source of the published AWP's. Back in 1992, major drug manufacturers told the inspector general's office that the *Red Book*, not the manufacturers, determined the AWP. But *Red Book* officials blamed the manufacturers.

The answers are the same today.

Phil Southerd, associate product manager of the *Red Book*, says it publishes prices that are faxed right from

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the manufacturers. "They're not our prices," he insists.

Ed Edelstein, editor of the *Blue Book*, says that, while some brand-name firms don't give him prices, generic firms do. "The AWP is the manufacturer's suggested wholesale price," he says. "It's our editorial policy to go along with that."

But Immunex, with a thriving generic cancer-drug business, says its average wholesale prices aren't its own. "The drug manufacturers have no control over the AWP's published . . .," says spokeswoman Valerie Dowell.

A maker of generic inhalants gives a different answer, but off the record: "The AWP's typically originate with the manufacturer."

More puzzling is the way generic AWP's stay at their lofty perches, or even rise, as competition forces a drug's true wholesale price into the abyss. "The reason this is happening," suggests Michael Neff, pharmacy program administrator of Medi-Cal, California's Medicaid agency, "is that most folks in a position to pay — even state Medicaid programs and HMOs — generally use AWP as a benchmark for reimbursement."

In 1993, the Bristol-Myers Squibb cancer drug Vepesid came off-patent, opening the market for a generic form called etoposide. A 100-milligram dose of Vepesid had an AWP of about \$136. The first generic etoposide was Gensia Pharmaceutical's, with a market price of about \$75, but the AWP of \$142.

The second generic to market, from Pharmacia, pushed the market price to \$60, but Pharmacia set an AWP around \$140. Today, the market price for 100 milligrams of etoposide is around \$35, but Gensia actually raised its AWP last year by about 10%.

When some drug salespeople visit a doctor, says another Medicaid administrator, the salesperson lets the doctor know that his product has a bigger spread between AWP and the real price than any other generic firm.

If manufacturers deliberately maintain lofty AWP's on their generic drugs, it directly profits their customers, not them. Of course, the drug makers might then gain market share and higher sales from their customers' over-utilization.

Indeed, for makers of generics, unreal average wholesale prices pose a classic social dilemma. If some, but not all, rectify their AWP's, the honest makers cut their own throats. "Manufacturers have told me that if they act on their own they'll dry up their own business," says Medi-Cal's Neff. "If I'm a buyer and one drug gives me 20% higher reimbursement, who am I going to go with?"

FALSE CLAIMS?

► Some of these firms make drugs, or bill insurers for drugs, that cost far less than the published Average Wholesale Price that Medicare and other insurers pay on claims. Says one wholesaler: "It may be legal, but it's certainly not ethical."

Company	Symbol	Exchange	Recent Price	Medicare Reimbursement Change Might Affect
Abbott Labs	ABT	NYSE	43 3/4	Medicare buys \$500 million of Lupron, also \$100s-of-millions of nutritionals
American Home Prods	AHOM	NNM	45 1/2	Medicare/Medicaid pay for 60% of firm's respiratory and infusion services revenues
American Oncology Resources	AORI	NNM	44 1/4	One-third of revenues from Medicare/Medicaid, chemo drugs a big profit center
Amgen	AMGN	NNM	60 1/2	\$75 million in Medicare payments for Neupogen = 10% of drug's U.S. sales
Baxter International	BAX	NYSE	46 3/4	Government demands rationale for its published prices on intravenous products
Bristol-Myers Squibb	BMJ	NYSE	88 3/4	Cancer drugs a mainstay; Medicare bought about 25% of U.S. sales of Taxol
Chiron	CHIR	NNM	97	Cancer drugs approx 5% of sales
Coram	CRH	NYSE	4 1/2	One-third of revenues from nutritional therapy; 27% of payments from Medicare/Medicaid
Gensia	GNSA	NNM	5 1/4	Largest product is generic etoposide; just got approval for generic doxorubicin
Immunex	IMNX	NNM	15 1/2	Cancer collaboration with American Home Products, leucovorin a \$20 million product
Lincare Holdings	LNCR	NNM	41 1/4	60% of revenues from Medicare/Medicaid, who are after firm's 85% gross margins
Omnicare	OCR	NYSE	56	Nursing home pharmacy gets 50% of sales from Medicaid/Medicare, expanding in infusion business
Pharmacia-Upjohn	PNU	NYSE	42 3/4	Cancer drugs approx. 9% of drug sales
Physician Practice Management	PHYN	NNM	49 3/4	45% of revenues from Medicare/Medicaid, chemo drugs a big profit center
RoTech	ROTC	NNM	19 3/4	50% of revenues Medicare/Medicaid; 6% from chemo and nutrition therapy

Source: Company reports

It's not rocket science; what's taken them so long?"

Some of the inspector general's investigators believe they've been played for fools. "We trusted the industry and the providers," says one investigator, off the record. "We didn't know how pervasive the discounting was. We thought it was available to just select providers."

Now, the Justice Department is serving "civil investigative demands" — a kind of subpoena in antitrust investigations — on manufacturers, asking them how those inaccurate AWP's wind up in the *Red Book* and *Blue Book*.

Baxter has received one, according to investigators, for its intravenous solutions, whose true wholesale prices — like those of rival Abbott — seem to be 90% below the average wholesale price. Baxter wouldn't comment to *Barron's*.

Some insurers, including Medicare, decree maximum prices for each generic drug, to avoid the alleged manipulation of AWP's. But it takes a year or so to establish a maximum price for new generics, and insurers haven't gotten around to setting prices for many doses.

"There definitely is over-utilization of these products," acknowledges a maker of inhalation drugs. "Because HCFA [the Health Care Financing Administration, the federal Medicare-Medicaid agency] is paying a somewhat arbitrary price, this has been discussed for almost three years."

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If most health-care providers can get much lower prices for pharmaceuticals than insurers do, is it any wonder that an industry wag says that "average wholesale price" really stands for "ain't what's paid"?

"The drug makers created false statements so that the doctors could make hundreds of millions of dollars," maintains an angry investigator. "If OIG doesn't get them, the Justice Department will."

Some investigators view the spreads guaranteed by extreme average wholesale prices as a kind of kickback to doctors, in violation of federal laws.

One group of infusion-industry veterans is reportedly considering attacking the problem by filing a private suit under the False Claims Act. This is the whistleblower law that allows citizens with knowledge of fraud against the government to sue on behalf of the government and share in the recovery.

Meanwhile, the cooler-headed policy-makers at the inspector general's office and in HCFA are reconsidering Medicare's drug reimbursement rules. They plan to propose their changes in the Federal Register soon.

"Medicare's been paying too much for our drugs," says deputy inspector general George Grob. "We're paying the window-sticker price when everybody else wants a discount and is getting it."

Tom Alt, of HCFA's Bureau of Policy Development, notes that any savings for Medicare will mean savings for beneficiaries, who are kicking in 20% co-payments at current Medicare prices.

Any reduction in reimbursement levels probably would have some effect on the firms that enjoy the spreads between everyday low wholesale prices and the average wholesale prices at which Uncle Sam reimburses them.

That includes oncology practice-management firms like American Oncology Resources and Physicians Reliance Network, which earn significant profits on the chemotherapy drugs they administer to cancer patients. Likewise, respiratory therapy and infusion firms like American HomePatient, Apria Healthcare, Coram Healthcare, Lincare Holding and RoTech Medical, which owe their sensational profit margins, to various degrees, to their drug spreads.

Then, there are the drug makers themselves, including Abbott, Baxter, Chiron, Gensia and Immunex — all with wide AWP spreads on their generic offerings.

Dr. H. Merrick Reese, the CEO of Physician Reliance, says he doubts that HCFA plans to cut reimbursement rates for cancer drugs, which he says his firm marks up only modestly.

More likely, Medicare will go after the inhalation drugs like albuterol, says Dr. Joseph Bales, who chairs the clinical practice committee of the American Society of Clinical Oncology.

ChemoLabs is doing what it can to ensure that the AWP tricksters start running out of fools. Located near Fort Worth Airport, Fanning's firm will supply chemotherapy drugs for insurers, shipping doses to oncologists as needed, and for a fraction of the average wholesale price.

And the most aggressive public insurers, including Medicaid programs in six states, are turning their backs on AWP.

They now base their drug payments on WAC—the Wholesale Acquisition Cost actually paid by medical-care providers.

Blue Book editor Edelstein warns, however, that this won't end the game. "Then the manufacturers will just start fooling around with that price," he warns.

For now, says Fanning, the ChemoLab pharmacist, the bonanza drug is etoposide. Someday, he expects to see a plaque saying: "This is the house that etoposide built." ■

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